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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,615	02/15/2002	Joseph C. Cauthen III	8442.0002-02	2841

22852 7590 08/29/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
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1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

8

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/075,615

Applicant(s)

CAUTHEN, JOSEPH C.

Examiner

Urmi Chattopadhyay

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 16 April 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Response to Amendment***

1. The Request for Approval of Drawing Change has been entered and approved by the examiner. The preliminary amendment filed 6/23/03 has been entered as Paper No. 6, thereby adding claims 21 and 22.
2. The preliminary amendment filed 4/16/02 has been entered as Paper No. 5. While all of the changes to the specification have been approved by the examiner, not all of the replacement paragraphs have been entered. Some of the replacement paragraph numbers do not correspond to the proper paragraph numbers in the specification. Applicant should resubmit these paragraph replacements with the proper paragraph numbers.

### ***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the length of the inside edge being less than the length of the outside edge requires support in the specification.

### ***Drawings***

4. The drawings are objected to because in Figure 9, the bottom "40" should be changed to --42-- for annulus and "41" should be deleted because the reference number is not mentioned in the specification.

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5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the length of the inside edge being less than the length of the outside edge (claim 4) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### *Claim Objections*

6. Claim 17 is objected to because of the following informalities: on line 3, either "a trapezoid" should be changed to --trapezoidal-- or "circular and curved" should be changed to --circle and curve--. Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the device being a repair device, does not reasonably provide enablement for the device being a therapeutic or prophylactic device. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

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9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 16, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 recites the limitation "said centralized vertical extension's horizontal axis" in line 4. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 11 recites the limitation "said material" in line 2. There is insufficient antecedent basis for this limitation in the claim. It appears that the claim should be dependent on claim 9, rather than on claim 8.

12. Claim 12 recites the limitation "said material" in line 2. There is insufficient antecedent basis for this limitation in the claim. It appears that the claim should be dependent on claim 11, rather than on claim 8.

13. Claim 13 recites the limitation "said internal cavity" in line 2. There is insufficient antecedent basis for this limitation in the claim. It appears that the claim should be dependent on claim 9, rather than on claim 8. If the dependency is changed to claim 9, applicant must cancel or amend claim 16 so not to have a duplicate claim.

14. Claim 19 is indefinite because it is dependent on itself. It appears that it should be dependent on claim 18, and will be interpreted to be so for examination purposes.

15. Claim 20 is indefinite because it is dependent on claim 23, which does not exist. It appears that it should be dependent on claim 21, and will be interpreted to be so for examination purposes.

*Claim Rejections - 35 USC § 102*

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 8-12, 15 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambrecht (USPN 6,425,919).

Lambrecht discloses a disc herniation constraining device with all the elements of claim 21. See Figures 29B-C for a device (12) for treating a spinal disc annulus having an aperture (16), the device comprising a biocompatible material (column 15, lines 58-63) for placement in and across the aperture such that the material forms a bridge providing a platform. Fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus will inherently traverse the bridge formed.

Claim 8, see Figure 29C and columns 15-16, lines 65-1 and column 19, lines 44-47 for flexible bladder (12').

Claim 9, see columns 15-16, lines 67-1 for bladder comprising a material enclosing an internal cavity by providing as a balloon.

Claim 10, see column 19, lines 44-47 for internal cavity being empty (unexpanded).

Claims 11, 12, 15 and 20, see column 15, lines 58-61 for bladder comprising the thin, flexible, biocompatible material ePTFE.

Claim 22, see column 6, lines 13-31 and column 19, lines 47-51 for means for fixing.

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***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 13, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht in view of Felt et al. (USPAP 2001/0004710 A1).

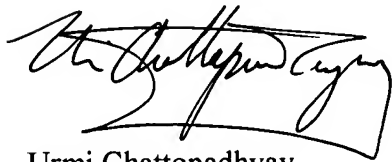
Lambrecht discloses a disc herniation constraining device with all the elements of claim 21, but is silent to the additional limitation of the internal cavity containing a biocompatible fluid, as required by claims 13 and 16, and of that fluid being a hydrogel, as required by claim 14. Felt et al. teaches a balloon (see [0102]) that is inserted into an aperture of a disc annulus and then filled with hydrogel to cure in order to permanently retain the hydrogel in apposition to the annulus aperture. See Figure 5, [0048] and [0233]-[0238]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Felt et al. to modify the device of Lambrecht by including hydrogel into the internal cavity of the balloon (12') in order to permanently retain the hydrogel, and therefore the implant, in position next to the aperture. Also, the examiner contends that by adding the hydrogel, upon curing, it will provide the device with added strength to resist tearing or breaking.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella  
Primary Examiner

uc

August 21, 2003